

REMARKS

Claims 16-20 and 24-32 are now pending. Applicant has amended claims 16, 18, and to further clarify their scope and subject matter.

Claim 24 has been amended to depend from claim 16 rather than cancelled claim 22. Claim 18 has also been amended to recite specific species within the genus *Streptococcus*, support for which may be found on page 9, lines 12-15.

Applicant notes that support for the functional language "wherein the viability of the bacteria in the composition does not decrease for a period of at least ten months when the composition is stored in an airtight container" in claims 16, 25 ("twelve months"), and 26 ("eighteen months") may be found in the table in Example 2, and page 10, lines 16-20, "The effective amount is a combination of these components, when mixed in the dry state, that provides for a composition where, under ambient conditions, the lifetime of the bacteria is substantial, having stability on the order of months to years." Applicant notes that the period of April 27, 1995 to February 7, 1996 is about 10 months, and that the period of April 27, 1995 to October 21, 1996 is about 18 months. Applicant also notes that "stability on the order of . . . years" implies stability for one year (12 months) or more.

Rejections under 35 USC §112, First Paragraph, Written Description

Claims 16-24 were rejected under 35 USC §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicant notes that the subject matter of a claim need not be described in the exact same terms (*in haec verba*) in the specification. See MPEP §2163.02. In addition, when a written description rejection is made, the examiner has the burden of providing specific reasons why the

person of ordinary skill in the art would not recognize the applicant's disclosure as a description of the invention defined by the claims, In re Wertheim, 191 USPQ 90, 96 (CCPA 1976). See MPEP §2163.04.

Claim 16 and dependent claims were rejected because the dry weight percent in the claims was alleged not to be described in the specification. The specification describes a dried bacterial compositions comprising dried viable bacteria, dried non-living yeast and a protein concentrate, primarily available commercially in dried form, page 6, line 21, and page 8, lines 1-12. Further support for the "dried" nature of the composition when admixed may be found on page 10, line 16 ("when mixed in a dry state"), page 8 lines 19-24, and page 18 lines 9-11. Given the fact that most dried prepared foods are produced by mixing dried ingredients in weight-ratio proportions, applicant submits that the person of ordinary skill in the art of food preparation would have no difficulty in understanding the "% total mass" language used in the application and claims to mean the % dry weight of the dry compositions. No reasoning has been given as to why this would not be clear from the specification. Thus, applicant requests that this rejection of claim 16 and dependant claims be reconsidered and withdrawn.

Claim 23 was rejected because the six month stability limitation was alleged not to be described by the specification. Although applicant believes that the description of the prior art compositions as being unable to sustain bacterial viability for 180 days, or six months, is sufficient to describe the "at least six month" limitation by differentiation, see p. 4, lines 11 - 16, applicant has cancelled the claim in the interest of accelerating prosecution. The new claimed time periods are clearly supported by the specification as indicated above. Therefore, applicant submits that this rejection is moot, and requests that it be withdrawn.

Rejections under 35 USC §112, Second Paragraph

Claims 18 and 23 were rejected under §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicant notes that the standard for examining definiteness under §112, second paragraph, described in MPEP § 2173.02, is whether the claims define the subject matter with a reasonable degree of particularity and distinctness, not whether more suitable language or modes of expression are available. As noted in MPEP § 2173.01, an applicant may use functional language, alternative expressions, negative limitation, or any style of expression or format of claims which makes clear the boundaries of the subject matter for which protection is sought. The fact that those boundaries may be broad or expansive is not grounds for a rejection of a lack of definiteness under §112, second paragraph, *In Re Miller*, 169 USPQ 597 (CCPA 1971), see MPEP § 2173.04. Applicant submits that the claims, as amended, are definite, and that the rejection of claims 18 and 23 under §112, second paragraph, should be reconsidered and withdrawn.

Claim 18 was rejected as indefinite for listing the genus *Streptococcus* in the enumerated viable bacterial strains for use in the present invention. In the interest of furthering prosecution, applicant has amended the claims to recite the acidiphilic *Streptococcus* species specifically described in the specification, as suggested in the Office action. Applicant respectfully requests that rejection be withdrawn.

Claim 23 was rejected because of the use of “substantially constant” to describe the viability of bacteria in the compositions of the present invention. Claim 23 has been cancelled. The present claims refer to bacterial viability in terms of no decrease in viability for specified times. Thus, applicant submits that this rejection is moot, and request that it be withdrawn.

Rejections under 35 U.S.C. § 102(b) and 103(a)

Claims 16, 17, 19, and 21 were rejected as under 102(b) as anticipated by, or, alternatively, under 103(a) as obvious over Levy in light of Prescott, et. al. Claim 16 and dependent claims 17-24 were rejected under 35 U.S.C. §103(a) as obvious over Levy taken with Prescott et al., and further taken with Jolly, Friend and El-Megeed et al. Applicant submits that these five references do not, when taken alone or in any combination, disclose each and every limitation of the claimed methods. Applicant further submits that no motivation to combine these references in the manner suggested exists in the prior art, or anywhere outside of the applicant's specification. Thus, the cited combination of references neither anticipates the claims nor creates a *prima facia* case of obviousness. Therefore, and applicant traverses these rejections, and requests that the rejections of claim 16 and all dependent claims under either 35 U.S.C. §102(b) or 35 U.S.C. 103(a) over the cited references be reconsidered and withdrawn.

The Levy reference describes a dietary supplement composition comprising 0.002 - 15% Bifidus bacteria, and the balance of the composition comprising 0 - ~100% "levure lactique" or "milk microbe" and 0 - ~100% "levure de biere" or "beer microbe." The Levy reference is not clear as to whether the "beer microbe" is living or non-living. Assuming that the "milk microbe" is a lactic acid bacteria the "beer microbe" is brewer's yeast, the Levy reference describes amounts of lactic acid bacteria in the composition in excess of 10% and/or amounts of brewer's yeast in the composition far in excess of 20%. The Levy composition does not include a protein concentrate, nor does the levy reference suggest the addition of a protein concentrate to its supplement. In addition, the Levy reference is silent regarding the storage stability and viability over time of the bacteria in the disclosed compositions.

The Prescott reference describes brewer's and baker's yeast in terms of production and protein content. Prescott also describes the use of brewer's yeast in animal feed and baker's yeast in dietary supplements. According to Prescott, brewer's yeast comprises about 40 % protein, and baker's yeast comprises about 50-55% protein. Prescott does not describe yeast as a particularly concentrated source of protein.

The Friend reference discusses the beneficial properties of *Lactobacillus* cultures, in general, including their nutritional and therapeutic benefits. The Friend reference also discusses the administration of *Lactobacillus* in wet cultured dairy products, specifically yogurt and milk. The Friend reference does not mention yeast. Nor does the Friend reference mention or suggest methods of preserving *Lactobacillus* activity in any sort of composition. Although the Friend reference does mention the benefits of *Lactobacillus* cultures in milk products, largely because of their ability to digest the sugar lactose, see page 128, Friend does not suggest combining *Lactobacillus* and whey protein concentrate.

The Jolly reference describes a method of producing "functional" protein from "impure" protein sources including yeast, bacteria, or other microorganisms. When yeast is used as a source of protein, it must first be lysed, and a crude protein extract produced by separating the protein solution from the "cell debris" (Col. 3, l. 27-30). The crude protein extract is then acidified and heated to produce denatured, precipitated proteins which are removed from the impure supernatant by centrifugation. These proteins are then hydrolyzed by incubation with proteolytic enzymes. After inactivation of the enzymes, the composition is spray dried. Only then is the protein "functional," and ready for use in food compositions. Nowhere in the Jolly reference is it suggested that whole, unprocessed yeast or other microorganisms be used as a source of protein in food, or that they should be mixed with the protein concentrate which is produced in the disclosure. To the

contrary, the entirety of the Jolly reference is directed towards the extraction, purification, and degradation of the protein from any suitable source (including yeast) to produce a uniform protein composition which is more soluble, heat and acid resistant, and smoother than natural proteins (Col. 5, l. 16-63).

The El Megeed reference describes “starter” formulations for the production of Egyptian Baladi and other Middle-eastern and Indian sub-continent fermented flat-breads. The formulations taught by El Megeed comprise dry lactic acid bacteria which exhibit enhanced lysine production, active, live dried baker’s yeast, wheat flour, and other baking ingredients, col. 3, line 27 - col. 4, line 11. The primary objective stated in the El Megeed reference is to provide a baking starter formulation which can be used to make bread by traditional Middle-eastern methods, col. 1, line 59 to col. 2, line 2. The standardization described by El Megeed in col. 11 pertains to the optimization of lysine-producing bacteria, active yeast, and flour for the production of Baladi bread.

§102(b) Rejection

Applicant first notes that in order to anticipate a claim, a reference must contain each and every element set forth in the claim, see MPEP §2131. Furthermore, in order to anticipate a range limitation in the claim, the reference must show an example within that range or a range overlapping, touching or within the claimed range. See MPEP §2131.03. Although a second reference may be used to explain the meaning of a term in a reference offered for anticipation purposes, or to show that an inherent characteristic exists in the reference, the secondary reference may not be used to expand the terms of the reference offered for anticipation. See MPEP 2131.01.

It is asserted that the disclosed compositions in the Levy reference anticipate the claimed dried bacterial compositions because A) the viable bacterial *bifidus* is present within the claimed

range, B) the Brewer's yeast component and lactic acid bacteria component of the composition are a "concentrated sources of protein," and thus equivalent to the claimed protein concentrate component. Applicant submits that this analysis is flawed because the claims cannot be so construed as to read out express range limitations for the purpose of examination, because all compositions disclosed in the Levy reference clearly do not contain the claimed percentages of bacteria and yeast, and because the characterization of yeast and bacteria as protein concentrates due to the assertion that they are "an art recognized source of concentrated protein" is not supported by the cited references and impermissibly reads out the protein concentrate element of the claimed compositions.

First, applicant notes that a claim should be interpreted by giving the terms within the claim their "plain meaning," unless otherwise defined in the specification. See MPEP 2111.01. Although the terms of the claim are to be given their broadest reasonable interpretation when undergoing examination in the patent office, In re Marosi, 218 USPQ 289 (Fed. Cir. 1983), it is impermissible and unreasonable to read limitations out of claims. See, e.g., Ex parte Kung, 17 USPQ2d 1545, 1548 (Bd. Pat. App. & Int. 1989), Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416, 420 (Fed. Cir. 1986). The claimed compositions comprise 0.1 to 10% dried viable bacteria, 2.5 to 20 % dried, non-living yeast, and 25 to 98 % protein concentrate. The limitation of 2.5 to 20 % dried, non-living yeast cannot be read to encompass 30%, 50% or 98% dried yeast without completely disregarding the upper range limit for yeast in the claims.

As admitted in the Office action of February 4, 2000, the compositions disclosed in Levy indicate a higher percentage of yeast than is claimed. The Levy reference discloses a composition comprising 0.002 to 15% *Bifidus* bacteria with the remainder of the composition comprising another lactic acid bacteria and brewer's yeast. Applicant notes that although the *bifidus* bacteria may be the focus of the Levy composition, it must be added to the amount of other lactic acid bacteria in the

Levy formula when determining the % bacteria in the composition. Thus, the Levy composition comprises lactic acid bacteria and brewer's yeast on a sliding continuum, wherein either the total amount of bacteria is over the claimed limit of 10%, or the amount of brewer's yeast is over the claimed limit of 20%. In fact, all specific examples of Levy disclosure exceed the claimed limit of 20% yeast. Thus none of the compositions described in Levy meet the % bacteria and non-living yeast requirements of the claimed composition. Therefore, the disclosed compositions of Levy cannot anticipate the current claims because they do not meet these express claim limitations.

In addition, Levy does not teach or suggest that a protein concentrate should be added to the disclosed formulation. The claimed compositions comprise a protein concentrate. Applicants submit that the plain meaning of this term for one of ordinary skill in the art is a relatively purified form of protein, rather than a "source" of protein. Thus, the third claimed component does not encompass powdered milk, blood meal, sawdust containing moderate amounts of lignin, or other putative "sources" of protein. It was argued in the last office action that yeast and bacteria are an "art recognized" concentrated source of protein, and thus are a protein concentrate. Although offered to support this point, the Prescott reference does not characterize yeast as a "concentrated" source of protein: rather yeast is simply described to contain protein in amounts up to 50% by weight. Of course, the other 50% weight of the dried yeast is carbohydrates, lipids, salts, nucleic acids, and other non-protein components. No reference is offered to support the assertion that one of ordinary skill in the nutrition supplement arts would characterize yeast as a "protein concentrate" rather than simply a source of protein. Thus, applicant submits that Levy reference cannot be interpreted to include a protein concentrate within its formulation.

In addition, as shown below, neither the Levy reference, nor any of the proffered secondary references, disclose or suggest the functional limitation of the claims that the viability of the bacteria

in the dried bacterial composition not decrease for at least 10 months when stored in an airtight container. In light of the fact that the Levy reference does not disclose compositions comprising the claimed amounts of bacteria and yeast, does not disclose a composition containing a protein concentrate, and does not disclose the functional limitations of the claims, applicant requests that the rejection of claims 16, 17, 19, and 21 under §102 (b) be reconsidered and withdrawn.

§103(a) Rejection

Applicant respectfully traverses the rejection of claims 16-24 as obvious under § 103 (a) over the Levy, Prescott, Jolly, Friend and El Megeed references. Applicant submits that these references, taken alone or in combination, do not suggest a dried, stable bacterial composition comprising a dried viable bacteria, a dried non-living yeast, and a protein concentrate, as claimed in the present invention. Applicant submits that no specific motivation for one of ordinary skill in the art to combine and modify the Levy, Prescott, El Megeed, Friend, and Jolly references exists in the prior art or elsewhere. Furthermore, applicant submits that even if one assumes that one of ordinary skill in the art would have been motivated to combine these references, they still do not teach compositions having the claimed proportions of ingredients and the claimed stability characteristics. Thus, a *prima facia* case of obviousness cannot be established, and the claims are not obvious under § 103 over the cited references.

Two well established principles of the law of obviousness under 35 U.S.C. § 103 are “(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination” and “(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.” See MPEP § 2141, Basic Considerations Which Apply to Obviousness Rejections. Springing from these requirements

are two other rules regarding the interpretation of prior art references: (1) as first explained in In re Gordon, 733 F.2d 900 (Fed. Cir. 1984), a prior art reference may not be modified in a way that would render the prior art invention unsatisfactory for its intended purpose (See MPEP § 2143.01), and (2) A prior art reference describing a composition of matter with similar parameters will only render a claimed similar composition obvious by "optimization" of the parameters if the parameter was art recognized as result-effective. In Re Antonie 195 USPQ 6 (CCPA 1977) (See MPEP § 2144.05, II. B.).

The proper framework for an analysis of the patentability of the present invention should not rest on the theory that an infinite number of nutrition specialists working in an infinite number of dietary laboratories producing every combination and permutation of natural dietary supplement ingredients would have produced the claimed invention, and that therefore it is obvious. Although virtually any natural product-based dietary supplement invention may be reconstructed by selecting individual ingredients contained in prior art compositions, such a reconstruction cannot be used to support an obviousness rejection without relying on impermissible hindsight unless a specific motivation exists in the prior art for one of ordinary skill to combine the particular elements of the invention in the claimed composition. As recently stated by the Court of Appeals for the Federal Circuit in In re Dembicczak:

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination" only by showing some objective teaching [leading to the combination]); In re Fine, 837 F.2d 1071, 1075, 5

USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board fell into the hindsight trap.

We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), *Para-Ordinance Mfg. v. SGS Imports Intern., Inc.*, 73 F.3d 1085, 1088, 37 USPQ2d 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the pertinent references," *Rouffet*, 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., *C.R. Bard*, 157 F.3d at 1352, 48 USPQ2d at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." . . . [50 USPQ2d 1614, 1617-1618 (Fed. Cir. 1999)].

Where an applicant has demonstrated new properties of a food additive not disclosed in the prior art, the courts of appeal have held that its use in another food for a purpose related to this new property is not obvious. In *In re Hayashibara and Sugimoto*, 188 USPQ 4 (Court of Claims and Patent Appeals 1975), applicants claimed a "low caloric food or drink containing a low caloric sweetening agent and an agent for adding solid volume, body, moisture absorbance, luster and increased viscosity, wherein both said agents consist essentially of lactitol." A cited French patent reference disclosed the use of lactitol in infant formula for the purpose of establishing a bifid flora in the gut of infants. The claims were rejected as obvious by the Examiner, who stated that "it would be obvious under 35 USC 103 to employ lactitol in a low caloric milk for children for its expected beneficial function." The Court of Claims and Patent Appeals responded:

Turning to the only rejection before us, which is for obviousness under § 103, we agree with appellants that there is nothing in the reference which would lead those of ordinary skill in the art to employ lactitol as appellants do in the products of claim 11. The reference does not teach lactitol as possessing any of the characteristics or functions on which appellants' claimed invention depends. The only function of lactitol which is set out in the reference is in a food for nursing infants, where it assists in the creation of a pure or nearly pure flora of bifid bacteria in the intestines, a result quite distinct from that achieved by appellants by using lactitol in a food or drink. Admittedly the reference does not disclose the sweetening properties of lactitol. We find nothing in the reference to suggest that lactitol has no caloric value when ingested as an ingredient of a food or drink. Nor is there any indication of lactitol's highly desirable attributes as a bodying agent, set forth above. Therefore, we find no basis for saying it would have been obvious to those of ordinary skill in the art to produce a sweetened and bodied food or drink of low caloric value by using lactitol as the agent for both sweetening and bodying, which is what claim 11 calls for. Furthermore, it is unrealistic to characterize an infant's formula as "low caloric." No one desires to reduce or minimize the caloric value of an infant's food or drink. The whole purpose of appellants' invention is to provide sweetening of no caloric value at all, in place of sugar, for the benefit of diabetics, who cannot tolerate sugar, and stout persons who should not.

Thus, the fact that an additive has been used in the production of some foodstuffs in the prior art is not a sufficient motivation for one of ordinary skill in the art to use that additive in any and all foodstuffs. In examining a claimed invention, an Examiner must also look towards the reasons for making the new combination of matter. If no specific reason to combine the specific elements in the claimed combination can be found in the art, then an obviousness rejection cannot be maintained.

The fact that an invention may be patentable despite the fact that it is a combination of old, simple elements has been reiterated many times by the appellate courts:

A patentable invention, within the ambit of 35 U.S.C. § 103, may result even if the inventor has, in effect, merely combined features, old in the art, for their known purpose, without producing anything beyond the results inherent in their use. Although we believe that appellant, here, has actually done more than this in making his combination, we also believe that a more proper, albeit not exclusive, inquiry in a case such as this is to look further as to the reasons for making the combination.

In Application of Sponnoble, 405 F.2d 578 (CCPA 1969).

There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination.

That knowledge cannot come from the applicant's invention itself. . . Oetiker's invention is simple. Simplicity is not inimical to patentability."

In re Oetiker, 24 USPQ2d 1443 (Fed. Cir. 1992).

No motivation has been shown for one of ordinary skill in the art to make the combination of Levy, Friend, Prescott, Jolly, and El Megeed suggested in the Office action. In fact, as detailed below, Jolly and El Megeed actually teach away from modifying the Levy formulation towards producing the claimed composition, as such modifications would be contrary to the stated objectives of those references. Thus, this combination cannot serve to establish a *prima facia* case of obviousness against the claimed methods.

Furthermore, the combined cited references do not overcome the deficiencies of the primary Levy reference. As described above, the Levy reference does not teach compositions with the claimed proportions of bacteria and yeast, nor does the Levy reference teach the inclusion of a protein concentrate into its formulation, nor does the Levy reference teach the functional stability limitation of the claims. Applicant submits that the proffered secondary references do not remedy these shortcomings of the Levy reference, and thus the combination, as a whole, does not render the claimed composition obvious. Thus, applicant requests that the rejections of claim 16 and defendant claims under §103 (a) as obvious over the Levy reference, alone or in combination with the cited secondary references, be reconsidered and withdrawn.

It was argued in the Office Action that one of ordinary skill in the art could have varied the proportions of brewer's yeast and bacteria to arrive at the claimed percentages. It was asserted that such a reformulation of the Levy compositions would be a simple "optimization" of the components, and thus within the ability of one of ordinary skill in the art. The "optimization" of the proportions of the ingredients or variable parameters in a prior art composition cannot be used to render a

claimed composition obvious unless the varied ingredients or parameters were art recognized as result-effective parameters. In re Antonie, 195 USPQ 6, 8 (CCPA 1977). This does not mean that a person of ordinary skill in the art might have been motivated to change the parameters for any purpose: such an assertion that one of ordinary skill in the art would have been motivated to vary any and all parameters to improve a system or composition's overall effectiveness or desirability is merely an extension of the forbidden "obvious to try" standard, In re O'Farrell, 7 USPQ2d 1673 (Fed. Cir. 1988). Rather, there must be some indication in the art that the person of ordinary skill in the art should vary the parameter to achieve the specific result disclosed or claimed by the applicant, Antonie, at 8. Nowhere in the Levy reference is it suggested that the storage stability of the described compositions is or could be dependant on the particular percentage of bacteria and brewer's yeast in the composition. In fact, Levy does not discuss the stability of the disclosed bacterial compositions at all. Nor do any of the other cited references suggest that the proportions of dried yeast and bacteria in a composition may be linked to maintaining bacterial viability. Therefore, the percentages of dried viable bacteria and dried non-living yeast cannot be considered recognized result-effective variables, as the cited references do not teach that extended bacterial viability may be realized by varying the percent bacteria and yeast in a composition. Thus, the claimed percentages of yeast and bacteria in the compositions of the invention are not an obvious "optimization" of the percentages disclosed in the Levy formulation.

The Jolly and Prescott references are offered in combination with the Levy reference to remedy the lack of a protein concentrate in the disclosed formulation. As mentioned above, the claimed protein concentrate is distinct from a mere "source" of protein. Thus, the assertion that the Prescott and Jolly references teach that yeast contains protein, and is thus equivalent to the "protein"

in the compositions utilized in the claimed methods, does nothing to remedy the lack of a protein concentrate in the Levy reference when compared to the claims compositions.

Furthermore, neither the Friend nor the Jolly reference suggests the addition of a protein concentrate to a bacteria and yeast composition. The Friend reference provides no impetus to add a protein concentrate to the compositions described in Levy, or to modify them in any other way. Friend does not describe nor suggest any methods of prolonging the viability of *Lactobacillus* cultures in dried bacterial compositions, nor does Friend even describe any such compositions. The Friend reference describes the use of bacterial cultures in milk and yogurt, neither of which is a protein concentrate. As described above, the general teachings of Friend that *Lactobacillus* cultures are "desirable" additions to nutritious product is not a sufficient motivating suggestion for one of ordinary skill in the art to make the specific combination of the claimed proportions of bacteria, yeast, and protein concentrate.

Likewise, the Jolly reference may not be used to suggest that whole yeast, whole bacteria, or any whole microorganism should be added to an edible composition. The Jolly reference teaches that these sources of protein are "crude" and "impure." Jolly further instructs those of skill in the art of prepared foods to extract, purify, and enzymatically modify protein from these natural sources in order to yield food products with superior processing, texture, and flavor qualities. Thus, Jolly teaches away from the use of whole dried non-living yeast in food compositions, instead encouraging the use of cell-free processed protein products in such foods. Therefore, a motive to add a protein concentrate to a bacteria and a non-living dried yeast to cannot be found in Jolly.

The El Megeed reference also provides no impetus to modify the formulations taught in Levy in order to obtain the claimed dried bacterial compositions with enhanced bacterial stability. El Megeed describes optimizing Baladi bread starter mixes for their use in traditional Middle-eastern

baking practices. This “optimization” taught by El Megeed is not directed towards preserving the viability of bacteria in dried compositions, and thus does not suggest to one in the art to vary the formula of Levy to obtain a composition in which bacterial viability is maintained, or that such a composition may be obtained by varying the percentages of bacteria or brewer’s yeast in the formula. In addition, a central, functional element of El Megeed’s starter formulations is active baking yeast. Thus, the teachings of El Megeed would teach away from a composition with dried non-living yeast. Nor does El Megeed assist the Levy reference in overcoming its lack of a protein concentrate: the entire focus of the El Megeed patent is on altering the protein content of breadstuffs by fermentation instead of supplementation with other protein sources, col. 6, lines 4 to 43. Thus, the combination of the Levy reference with El Megeed does nothing to remedy the deficiencies of the Levy reference. Thus, the Levy reference does not teach the compositions used in the claimed invention, even when combined with the cited secondary references.

In this case, the combination of elements in the composition administered in the claimed methods is neither taught nor suggested by the cited art. The Examiner’s purported suggestion to modify the composition of Levy by optimization is flawed as the basis for rejection of the pending claims because no clear suggestion or motivation in the art exists to alter the proportions of dried yeast and bacterial culture to increase bacterial viability, and no motivation exists in the cited art to add the protein concentrate component of the claims. In addition, there is no indication in the cited references that such a combination would have the claimed effect of preserving bacterial viability for a period of at least ten months when stored in an airtight container. To reach a conclusion of obviousness for any and all combinations of a dried bacteria, a dried non-living yeast, and a protein concentrate is clearly erroneous result in light of the above cited precedent. Because the cited references do not teach or suggest, whether alone or in combination, a dried bacterial composition

which maintains bacterial viability for a period of ten months or more and which contains 0.1 to 10% dried viable bacteria, 2.5 to 20% dried non-living yeast, and 25 to 98% protein concentrate, it is respectfully submitted that those references do not render obvious the subject matter defined by claims 16-20 and 24-27. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Respectfully submitted,

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